

February 17, 2015



# The British Standards Institution Classifies Arch Therapeutics' AC5(TM) as a Medical Device Within the European Union

## AC5 Surgical Hemostatic Device(TM) Fulfills Definition of a Medical Device CE Mark Designation

WELLESLEY, MA -- (Marketwired) -- 02/17/15 -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), a medical device company and developer of the AC5 Surgical Hemostatic Device™ (AC5™), a novel product aimed at controlling bleeding and fluid loss in order to provide faster and safer surgical and interventional care, has received confirmation from The British Standards Institution (BSI), a Notified Body in the European Union (EU), that AC5 fulfills the definition of a medical device within the EU and will be classified as such in consideration for CE mark designation. Eventually obtaining the CE mark for AC5 would allow the Company to sell the product within the EU.

BSI reviewed the scientific information provided by Arch detailing that the mechanism of hemostasis activity of AC5 results from the self-assembly of the product into a mechanical barrier, which seals the tissue to stop bleeding. BSI has concluded that the primary mode of action is physical and fulfills the definition of a medical device. BSI has further concluded that AC5 was without ancillary medicinal activity.

A Notified Body such as BSI is an organization that has been accredited by a member state of the EU to determine whether a product meets certain preordained standards to receive a CE mark designation. Arch intends to enter the hemostasis and sealant market in Europe.

Terrence Norchi, MD, President and CEO of Arch Therapeutics, stated, "This notification from BSI is an important milestone for the Company. It confirms what we have long believed about AC5's properties, specifically with regard to its underlying barrier mechanism of action, which we believe differentiates AC5 from currently available products. I am pleased that we have received this ruling, which removes a significant risk and potential burden from our commercialization strategy."

### **About BSI**

BSI's mission is to ensure patient safety while supporting timely access to global medical device technology. They provide thorough, responsive, predictable conformity assessments, evaluations and certifications that are recognized and accepted worldwide. To learn more, visit [medicaldevices.bsigroup.com](http://medicaldevices.bsigroup.com)

### **About Arch Therapeutics, Inc.**

Arch Therapeutics, Inc. is a medical device company developing a novel approach to stop

bleeding (hemostasis) and control leaking (sealant) during surgery and trauma care. Arch is developing products based on an innovative self-assembling peptide technology platform to make surgery and interventional care faster and safer for patients. Arch's flagship development stage product candidate, known as AC5 Surgical Hemostatic Device, is being designed to achieve hemostasis in minimally invasive and open surgical procedures.

Find out more at [www.archtherapeutics.com](http://www.archtherapeutics.com).

***Notice Regarding Forward-Looking Statements***

This news release contains "forward-looking statements" as that term is defined in Section 27(a) of the Securities Act of 1933, as amended, and Section 21(e) of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements and include any statements regarding beliefs, plans, expectations or intentions regarding the future. Such forward-looking statements include, among other things, references to novel technologies and methods, our business and product development plans and projections, or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with developing new products or technologies and operating as a development stage company, our ability to retain important members of our management team and attract other qualified personnel, our ability to raise the additional funding we will need to continue to pursue our business and product development plans, our ability to develop and commercialize products based on our technology platform, and market conditions. These forward-looking statements are made as of the date of this news release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Although we believe that any beliefs, plans, expectations and intentions contained in this press release are reasonable, there can be no assurance that any such beliefs, plans, expectations or intentions will prove to be accurate. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the reports and other documents we file with the SEC, available at [www.sec.gov](http://www.sec.gov).

On Behalf of the Board,  
Terrence W. Norchi, MD  
Arch Therapeutics, Inc.

***Contact:***

ARTH Investor Relations  
Toll Free: +1-855-340-ARTH (2784) (US and Canada)  
Email: [investors@archtherapeutics.com](mailto:investors@archtherapeutics.com)  
Website: [www.archtherapeutics.com](http://www.archtherapeutics.com)

Or

Richard Davis  
Chief Financial Officer  
Arch Therapeutics, Inc.  
Phone: 617-431-2308

Email: [rdavis@archtherapeutics.com](mailto:rdavis@archtherapeutics.com)

Website: [www.archtherapeutics.com](http://www.archtherapeutics.com)

Source: Arch Therapeutics, Inc.